EXHIBIT 15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	14/699,567
Applicant:	Declan Walsh et al.
Filed:	April 29, 2015
Title:	DOSE COUNTER FOR INHALER AND METHOD FOR COUNTING DOSES
T.C./A.U.:	2876
Examiner:	Daniel A. Hess
Confirmation No.:	6857
Docket No.:	TEVE-139US6

AMENDMENT

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action dated June 17, 2016, please amend the above-identified application as follows:

☐ **Amendments to the Specification** begin on page of this paper.

☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet(s).

☐ **Amendments to the Abstract** are on page of this paper. A clean version of the Abstract is on page of this paper.

☒ **Remarks/Arguments** begin on page 6 of this paper.

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (Currently Amended) A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

~~an incremental counting system for counting doses, the incremental counting system having a main body, an actuator arranged to be driven in response to canister motion and to drive an incremental output member in response to canister motion, the actuator and incremental output member being configured to have predetermined canister fire and count configurations in a canister fire sequence, the canister fire configuration being determined by a position of the actuator relative to a datum at which the canister fires medicament and the count configuration being determined by a position of the actuator relative to the datum at which the incremental counting system makes an incremental count, wherein the actuator is arranged to reach a position thereof in the count configuration at or after a position thereof in the canister fire configuration~~

a ratchet wheel having a plurality of circumferentially spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

a dosage indicator associated with the count pawl,

wherein the canister fire sequence comprises a canister fire configuration and a count configuration wherein:

in the canister fire configuration the actuator pawl and ratchet wheel are in a first position at which the canister fires medicament, and

in the count configuration the actuator pawl is in the first position or in a second position which is just after the first position, and in the count configuration the count pawl has just resiliently jumped over the second tooth and the dosage indicator has indicated a count.

2. (Currently Amended) A dose counter as claimed in Claim 1 in which the ~~actuator and incremental counting system are arranged such that the~~ actuator is displaced less than 1 mm relative to the ~~main~~ body between its locations in the canister fire and count configurations.

3. (Cancelled)

4. (Currently Amended) A dose counter as claimed in Claim 1 ~~in which the incremental counting system includes a tape counter~~ wherein the dosage indicator ~~having~~ includes a tape with incremental dose indicia located thereon, the tape being positioned on a tape stock bobbin and arranged to unwind therefrom.

5. (Currently Amended) A dose counter as claimed in Claim 1 in which the actuator and ~~incremental output member~~ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ratchet wheel~~incremental output member~~, a reset configuration at which the actuator is brought into engagement with the ratchet wheel ~~incremental output member~~ during ~~a~~ the canister fire sequence, and an end configuration at which the actuator disengages from the ratchet wheel ~~incremental output member~~ during ~~a~~ the canister fire sequence.

6. (Currently Amended) A dose counter as claimed in claim 5 in which:

(a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;

(b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; ~~and/~~or

(c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

7. (Currently Amended) A dose counter as claimed in Claim 5 in which the ~~main~~ body includes a formation for forcing the actuator to disengage from the ~~incremental output member~~ratchet wheel when the actuator is moved past the end configuration.

8. (Currently Amended) A dose counter as claimed in claim 1 ~~which includes a counter pawl, the counter pawl having a tooth arranged to engage the incremental output~~

~~member~~, wherein the count pawl ~~tooth and incremental output member being~~ and the ratchet wheel are arranged to permit one way incremental relative motion therebetween.

9. (Currently Amended) A dose counter as claimed in Claim 8 in which the actuator and ~~incremental output member~~ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ~~incremental output member~~ratchet wheel, a reset configuration at which the actuator is brought into engagement with the ratchet wheel ~~incremental output member~~ during ~~a~~ the canister fire sequence, and an end configuration at which the actuator disengages from the ratchet wheel ~~incremental output member~~ during ~~a~~ the canister fire sequence and in which the ~~counter~~ count pawl is substantially fixedly mounted on the ~~main~~ body ~~of the incremental counting system~~ and in which ~~counter~~ count pawl is arranged to be capable of repeatedly engaging ~~equi spaced~~the teeth of the ~~incremental output member~~ratchet wheel in anti-back drive interlock configurations as the dose counter is operated, the ~~counter~~ count pawl being positioned so that the ~~incremental output member~~ratchet wheel is halfway, or substantially halfway, moved from one anti-back interlock configuration to the next when the actuator and ~~incremental output member~~ratchet wheel are in the end configuration thereof.

10. (Currently Amended) An inhaler comprising the ~~main~~ body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1.

11. (Currently Amended) An inhaler as claimed in Claim 10 in which the ~~main~~ body includes a canister-receiving portion and a separate counter chamber; the ~~main~~ body, ~~incremental output member~~ ratchet wheel and actuator being located inside the counter chamber, the ~~main~~ body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

12. (New) The dose counter as claimed in Claim 4, wherein the incremental dose indicia on the tape is in the form of even numbers and the body includes a dose marker that points to a location either at one of the even numbers or between two adjacent even numbers.

13. (New) A dose counter as claimed in claim 5 in which:

(a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;

(b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; and

(c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

Remarks/Arguments:

Claim Status

Claims 1, 2 and 4-11 are pending and stand rejected. Features of claim 3 have been incorporated into sole independent claim 1. Claim 3 has been cancelled without prejudice or disclaimer of the subject matter thereof. Support for additional amendments to claim 1 may be found in FIGs. 10A-10F and their supporting description (see, e.g., paragraphs 0154-0156 of the publication of the instant application). Various other claims have been amended for antecedent basis purposes. Claim 12 is new, and support for that claim may be found in FIG. 6E and its supporting description. Claim 13 is new and support for that claim may be found in original claim 6. No new matter has been added.

Claim Rejections

Claim 6 stands rejected under 35 U.S.C. 112 as being indefinite because it includes the phrase "and/or." The Applicant has replaced this phrase with the term "or." Withdrawal of this rejection is respectfully requested.

Claims 1-5 and 7-11 stand rejected as either lacking novelty or being obvious over U.S. Patent No. 6,446,627 to Bowman. The Applicant respectfully requests reconsideration of these rejections for the reasons set forth hereinafter.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In establishing a prima facie case of obviousness, "all of the claim limitations must be considered." M.P.E.P. §2143. Amended independent claim 1 recites at least the following features that are neither disclosed nor suggested by the cited reference:

> wherein the canister fire sequence comprises a canister fire configuration and a count configuration wherein: in the canister fire configuration the actuator pawl and ratchet wheel are in a first position at which the canister fires medicament, and in the count configuration the actuator pawl is in the first position or in a second position which is just after the first position, and in the count configuration the count pawl has just resiliently jumped over the second tooth and the dosage indicator has indicated a count.

The invention recited in amended claim 1 generally relates to the relationship between when the count pawl "clicks" over a tooth of the ratchet wheel and when the canister fires.

As can be seen in Figures 10D and 10E of the instant invention, which are reproduced below, by way of background to the claimed invention, when the actuator is depressed fully, so as to fire the metered valve (not shown) inside the canister, the actuator pawl 80 pulls down on one of the teeth 140 of the ratchet wheel 94 and rotates the wheel 94 anticlockwise. The dose counter also includes a separate count pawl 138. The actuator pawl 80 and count pawl 138 are engaged with different teeth 140 as shown in Figure 10E (defined in the amended claims as a first tooth and a second tooth, respectively). The count pawl 138 is associated with the counter, which can include a tape displaying numbers. The ratchet wheel 94 can rotate so as to jump one tooth beyond the count pawl 138 (compare FIGs. 10D and 10E), thereby winding the tape a distance incrementally relative to the dose marker on the dose counter chamber so as to indicate that a dose has been used.

FIG. 10D

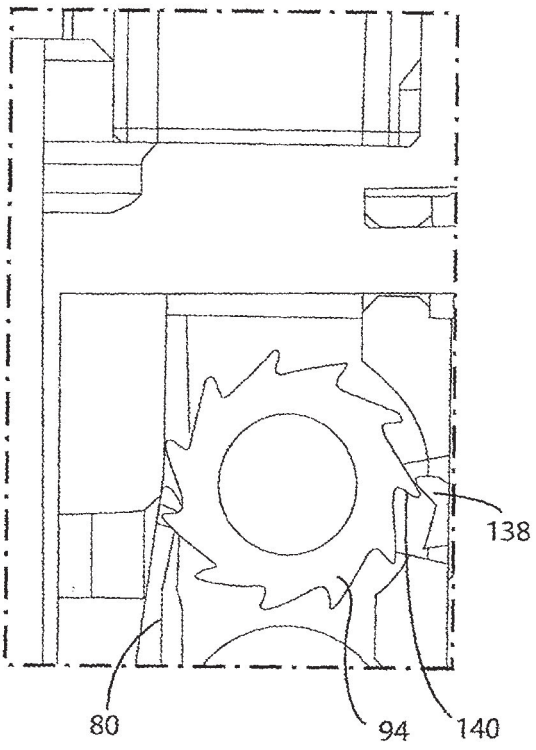

FIG. 10E

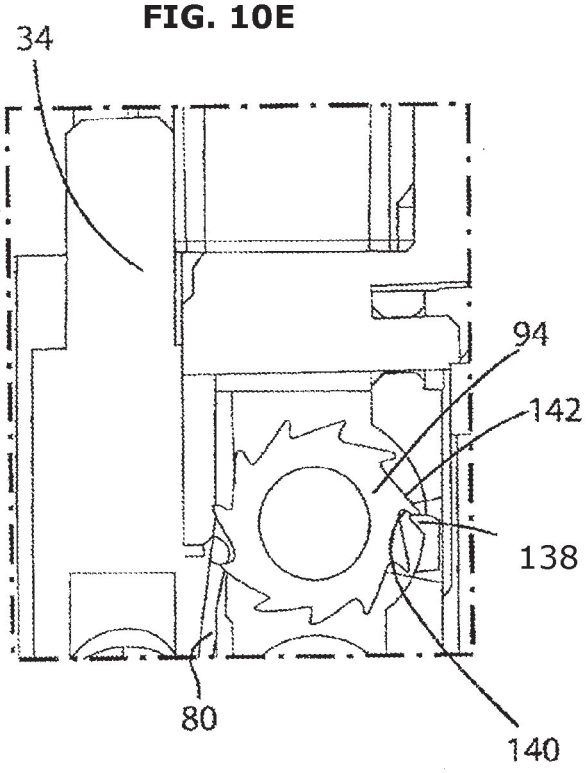

Figure 10E (above) shows the count configuration in which the actuator pawl 80 has rotated the ratchet wheel 94 by the distance circumferentially angularly between two of the teeth, such that the count pawl 138 has just finished riding along a forward surface 142 of one of the teeth and has resiliently jumped over the tooth into engagement with the back surface 140 of the next tooth. Accordingly, in this count configuration, a sufficiently long stroke

movement of the system has occurred that the tape of the dose counter will just have counted. It has been found by the Applicant that, although the count configuration can happen further on than the fire configuration, counting is highly reliable, with less than one in 50 failed counts per million. This is at least partially due to momentum effects and to the canister releasing some back pressure on the user in some embodiments as its internal metering valve fires.

While the image in Figure 4 of Bowman may appear similar to the images in the present application, the accompanying description of Bowman discloses nothing about when its fixed pawl rides over the teeth of its ratchet wheel relative to their position when the canister fires. Instead, the arrangement in Figures 4 and 6 of Bowman is said to be a conventional ratchet arrangement in which pawl acts to prevent reverse rotation of the ratchet wheel. The Applicant notes that indexing and counting in Bowman refers to the movement of the tape, not the action of the fixed pawl.

Additionally, there is nothing in Bowman that provides any clear and unmistakable direction that a count pawl can be used in conjunction with an actuator pawl as defined by claim 1 of the present invention. Moreover, Bowman may not have appreciated the importance of the count sequence of the present invention because the main embodiment of Bowman uses a wrap-spring clutch, which provide a continuous, rather than step-wise, restriction on reverse rotation.

The present invention provides highly reliable counting, with less than one in 50 failed counts per million. The Applicant submits that this could not have been predicted based upon Bowman alone.

Accordingly, because claim 1 includes features that are neither disclosed nor suggested by the cited reference, neither anticipation nor *prima facie* obviousness can be established based on the cited reference. The dependent claims that stand rejected should also be allowed at least as being dependent upon an allowable base claim. Reconsideration of claims 1, 2 and 4-11, and allowance of new claims 12 and 13, is respectfully requested.

Conclusion

In view of the remarks set forth above, the Applicant respectfully submits that this application is now in condition for allowance, which action is respectfully requested. If the Examiner believes an interview will advance the prosecution of this application, it is respectfully requested that the Examiner contact the undersigned to arrange the same.

Respectfully submitted,

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Dated: September 9, 2016

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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